Senate Study Bill 3074 - Introduced

SENATE/HOUSE FILE _____
BY (PROPOSED BOARD OF PHARMACY BILL)

A BILL FOR

- 1 An Act relating to the electronic prescribing of prescription
- 2 drugs including controlled substances, making penalties
- 3 applicable, and providing penalties.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 1 Section 1. Section 124.308, Code 2018, is amended by
- 2 striking the section and inserting in lieu thereof the
- 3 following:
- 4 124.308 Prescriptions.
- 5 l. Except when dispensed directly by a practitioner to an
- 6 ultimate user, a prescription drug as defined in section 155A.3
- 7 that is a controlled substance shall not be dispensed without
- 8 a prescription, unless such prescription is authorized by a
- 9 practitioner and complies with this section, section 155A.27,
- 10 applicable federal law and regulation, and rules of the board.
- 11 2. a. Beginning July 1, 2019, every prescription issued
- 12 for a controlled substance shall be transmitted electronically
- 13 as an electronic prescription pursuant to the requirements in
- 14 subsection 2, paragraph "b", unless exempt under subsection 2,
- 15 paragraph "c".
- 16 b. Except for prescriptions identified in paragraph c,
- 17 a prescription that is transmitted pursuant to paragraph "a"
- 18 shall be transmitted to a pharmacy by a practitioner or the
- 19 practitioner's authorized agent in compliance with federal
- 20 law and regulation for electronic prescriptions of controlled
- 21 substances. The practitioner's electronic prescription system
- 22 and the receiving pharmacy's dispensing system shall comply
- 23 with federal law and regulation for electronic prescriptions of
- 24 controlled substances.
- 25 c. Paragraph "b" shall not apply to any of the following:
- 26 (1) A prescription for a patient residing in a nursing home,
- 27 long-term care facility, correctional facility, or jail.
- 28 (2) A prescription authorized by a licensed veterinarian.
- 29 (3) A prescription dispensed by a department of veterans
- 30 affairs pharmacy.
- 31 (4) A prescription requiring information that makes
- 32 electronic submission impractical, such as complicated or
- 33 lengthy directions for use or attachments.
- 34 (5) A prescription for a compounded preparation containing
- 35 two or more components.

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- 1 (6) A prescription issued in response to a public health
- 2 emergency in a situation where a non-patient specific
- 3 prescription would be permitted.
- 4 (7) A prescription issued pursuant to an established and
- 5 valid collaborative practice agreement, standing order, or drug
- 6 research protocol.
- 7 (8) A prescription issued during a temporary technical or
- 8 electronic failure at the prescriber's or pharmacy's location.
- 9 (9) A prescription issued in an emergency situation
- 10 pursuant to federal law and regulation rules of the board.
- 11 d. A practitioner, as defined in section 124.101, subsection
- 12 27, paragraph "a", who violates paragraph "a" is subject
- 13 to an administrative penalty of two hundred fifty dollars
- 14 per violation, up to a maximum of five thousand dollars per
- 15 calendar year. The assessment of an administrative penalty
- 16 pursuant to this paragraph by the appropriate licensing board
- 17 of the practitioner alleged to have violated paragraph "a"
- 18 shall not be considered a disciplinary action and shall not be
- 19 released or reported as discipline. A practitioner may appeal
- 20 the assessment of an administrative penalty pursuant to this
- 21 paragraph, which shall initiate a contested case proceeding
- 22 under chapter 17A. A penalty collected pursuant to this
- 23 paragraph shall be deposited into the drug information program
- 24 fund established pursuant to section 124.557. The board shall
- 25 be notified of any administrative penalties assessed by the
- 26 appropriate professional licensing board and deposited into the
- 27 drug information program fund under this paragraph.
- 28 3. A prescription issued prior to July 1, 2019, or a
- 29 prescription that is exempt from the electronic prescription
- 30 requirement in subsection 2, paragraph c, may be transmitted
- 31 by a practitioner or the practitioner's authorized agent to a
- 32 pharmacy in any of the following ways:
- 33 a. Electronically, if transmitted in accordance with
- 34 the requirements for electronic prescriptions pursuant to
- 35 subsection 2.

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- 1 b. By facsimile for a schedule III, IV, or V controlled
- 2 substance, or for a schedule II controlled substance only
- 3 pursuant to federal law and regulation and rules of the board.
- 4 c. Orally for a schedule III, IV, or V controlled substance,
- 5 or for a schedule II controlled substance only in an emergency
- $\boldsymbol{6}$ situation pursuant to federal regulation and rules of the
- 7 board.
- 8 d. By providing an original signed prescription to a patient
- 9 or a patient's authorized representative.
- 10 4. If permitted by federal law and in accordance with
- 11 federal requirements, an electronic or facsimile prescription
- 12 shall serve as the original signed prescription and the
- 13 practitioner shall not provide a patient, a patient's
- 14 authorized representative, or the dispensing pharmacy with a
- 15 signed, written prescription. An original signed prescription
- 16 shall be retained for a minimum of two years from the date of
- 17 the latest dispensing or refill of the prescription.
- 18 5. A prescription for a schedule II controlled substance
- 19 shall not be filled more than six months after the date
- 20 of issuance. A prescription for a schedule II controlled
- 21 substance shall not be refilled.
- 22 6. A prescription for a schedule III, IV, or V controlled
- 23 substance shall not be filled or refilled more than six months
- 24 after the date on which the prescription was issued or be
- 25 refilled more than five times.
- 7. A controlled substance shall not be distributed or
- 27 dispensed other than for a medical purpose.
- 28 8. A practitioner, medical group, or pharmacy that is unable
- 29 to timely comply with the electronic prescribing requirements
- 30 in subsection 2, paragraph b'', may petition the board for an
- 31 exemption from the requirements based upon economic hardship,
- 32 technical limitations that the practitioner, medical group, or
- 33 pharmacy cannot control, or other exceptional circumstances.
- 34 The board shall adopt rules establishing the form and specific
- 35 information to be included in a request for an exemption

1 and the specific criteria to be considered by the board in

- 2 determining whether to approve a request for an exemption. The
- 3 board may approve an exemption for a period of time determined
- 4 by the board not to exceed one year from the date of approval,
- 5 and may be renewed annually upon request subject to board
- 6 approval.
- 7 Sec. 2. Section 155A.27, Code 2018, is amended by striking
- 8 the section and inserting in lieu thereof the following:
- 9 155A.27 Requirements for prescription.
- 10 l. Except when dispensed directly by a prescriber to an
- 11 ultimate user, a prescription drug shall not be dispensed
- 12 without a prescription, authorized by a prescriber, and based
- 13 on a valid patient-prescriber relationship.
- 2. a. Beginning July 1, 2019, every prescription issued for
- 15 a prescription drug shall be transmitted electronically as an
- 16 electronic prescription to a pharmacy by a prescriber or the
- 17 prescriber's authorized agent unless exempt under paragraph 18 b.
- 19 b. Paragraph "a" shall not apply to any of the following:
- 20 (1) A prescription for a patient residing in a nursing home,
- 21 long-term care facility, correctional facility, or jail.
- 22 (2) A prescription authorized by a licensed veterinarian.
- 23 (3) A prescription for a device.
- 24 (4) A prescription dispensed by a department of veterans
- 25 affairs pharmacy.
- 26 (5) A prescription requiring information that makes
- 27 electronic transmission impractical, such as complicated or
- 28 lengthy directions for use or attachments.
- 29 (6) A prescription for a compounded preparation containing
- 30 two or more components.
- 31 (7) A prescription issued in response to a public health
- 32 emergency in a situation where a non-patient specific
- 33 prescription would be permitted.
- 34 (8) A prescription issued for an opioid antagonist pursuant
- 35 to section 135.190 or a prescription issued for epinephrine

1 pursuant to section 135.185.

- 2 (9) A prescription issued during a temporary technical
- 3 or electronic failure at the location of the prescriber or
- 4 pharmacy.
- 5 (10) A prescription issued pursuant to an established and
- 6 valid collaborative practice agreement, standing order, or drug
- 7 research protocol.
- 8 (11) A prescription issued in an emergency situation
- 9 pursuant to federal law and regulation and rules of the board.
- 10 c. A practitioner, as defined in section 124.101, subsection
- 11 27, paragraph "a", who violates paragraph "a" is subject
- 12 to an administrative penalty of two hundred fifty dollars
- 13 per violation, up to a maximum of five thousand dollars per
- 14 calendar year. The assessment of an administrative penalty
- 15 pursuant to this paragraph by the appropriate licensing board
- 16 of the practitioner alleged to have violated paragraph "a"
- 17 shall not be considered a disciplinary action and shall not be
- 18 released or reported as discipline. A practitioner may appeal
- 19 the assessment of an administrative penalty pursuant to this
- 20 paragraph, which shall initiate a contested case proceeding
- 21 under chapter 17A. A penalty collected pursuant to this
- 22 paragraph shall be deposited into the drug information program
- 23 fund established pursuant to section 124.557. The board shall
- 24 be notified of any administrative penalties assessed by the
- 25 appropriate professional licensing board and deposited into the
- 26 drug information program fund under this paragraph.
- 27 3. For prescriptions issued prior to July 1, 2019, or
- 28 for prescriptions exempt from the electronic prescription
- 29 requirement in subsection 2, paragraph "b", a prescriber or the
- 30 prescriber's authorized agent may transmit a prescription for a
- 31 prescription drug to a pharmacy by any of the following means:
- 32 a. Electronically.
- 33 b. By facsimile.
- 34 c. Orally.
- 35 d. By providing an original signed prescription to a patient

1 or a patient's authorized representative.

- 2 4. A prescription shall be issued in compliance with
- 3 this subsection. Regardless of the means of transmission, a
- 4 prescriber shall provide verbal verification of a prescription
- 5 upon request of the pharmacy.
- If written, electronic, or facsimile, each prescription
- 7 shall contain all of the following:
- (1) The date of issue.
- (2) The name and address of the patient for whom, or the
- 10 owner of the animal for which, the drug is dispensed.
- (3) The name, strength, and quantity of the drug prescribed. 11
- 12 (4) The directions for use of the drug, medicine, or device
- 13 prescribed.
- (5) The name, address, and written or electronic signature 14
- 15 of the prescriber issuing the prescription.
- 16 (6) The federal drug enforcement administration number, if
- 17 required under chapter 124.
- 18 If electronic, each prescription shall comply with all
- 19 of the following:
- (1) The prescriber shall ensure that the electronic system
- 21 used to transmit the electronic prescription has adequate
- 22 security and safeguards designed to prevent and detect
- 23 unauthorized access, modification, or manipulation of the
- 24 prescription.
- (2) Notwithstanding paragraph "a", subparagraph (5),
- 26 for prescriptions that are not controlled substances, if
- 27 transmitted by an authorized agent, the electronic prescription
- 28 shall not require the written or electronic signature of the
- 29 prescriber issuing the prescription.
- If facsimile, in addition to the requirements of 30
- 31 paragraph "a", each prescription shall contain all of the
- 32 following:
- (1) The identification number of the facsimile machine 33
- 34 which is used to transmit the prescription.
- (2) The date and time of transmission of the prescription. 35

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- 1 (3) The name, address, telephone number, and facsimile 2 number of the pharmacy to which the prescription is being 3 transmitted.
- 4 d. If oral, the prescriber issuing the prescription
- 5 shall furnish the same information required for a written
- 6 prescription, except for the written signature and address
- 7 of the prescriber. Upon receipt of an oral prescription,
- 8 the recipient shall promptly reduce the oral prescription to
- 9 a written format by recording the information required in a
- 10 written prescription.
- 11 e. A prescription transmitted by electronic, facsimile,
- 12 or oral means by a prescriber's agent shall also include
- 13 the name and title of the prescriber's agent completing the
- 14 transmission.
- 15 5. An electronic, facsimile, or oral prescription
- 16 shall serve as the original signed prescription and the
- 17 prescriber shall not provide a patient, a patient's authorized
- 18 representative, or the dispensing pharmacist with a signed
- 19 written prescription. Prescription records shall be retained
- 20 pursuant to rules of the board.
- 21 6. This section shall not prohibit a pharmacist,
- 22 in exercising the pharmacist's professional judgment,
- 23 from dispensing, at one time, additional quantities of a
- 24 prescription drug, with the exception of a prescription drug
- 25 that is a controlled substance as defined in section 124.101,
- 26 up to the total number of dosage units authorized by the
- 27 prescriber on the original prescription and any refills of
- 28 the prescription, not to exceed a ninety-day supply of the
- 29 prescription drug as specified on the prescription.
- 30 7. A prescriber, medical group, institution, or pharmacy
- 31 that is unable to timely comply with the electronic prescribing
- 32 requirements in subsection 2, paragraph "a", may petition
- 33 the board for an exemption from the requirements based upon
- 34 economic hardship, technical limitations that the prescriber,
- 35 medical group, institution, or pharmacy cannot control, or

1 other exceptional circumstances. The board shall adopt rules

- 2 establishing the form and specific information to be included
- 3 in a request for an exemption and the specific criteria to be
- 4 considered by the board in determining whether to approve a
- 5 request for an exemption. The board may approve an exemption
- 6 for a period of time determined by the board, not to exceed one
- 7 year from the date of approval, and may be annually renewed
- 8 subject to board approval upon request.
- Sec. 3. Section 155A.29, subsection 4, Code 2018, is amended
- 10 to read as follows:
- 4. An authorization to refill a prescription drug order may 11
- 12 shall be transmitted to a pharmacist pharmacy by a prescriber
- 13 or the prescriber's authorized agent through word of mouth,
- 14 note, telephone, facsimile, or other means of communication
- 15 initiated by or directed by the practitioner. The transmission
- 16 shall include the information required pursuant to section
- 17 155A.27, except that prescription drug orders for controlled
- 18 substances shall be transmitted pursuant to section 124.308,
- 19 and, if not transmitted directly by the practitioner,
- 20 shall identify by also include the name and title of the
- 21 practitioner's agent completing the transmission.
- 22 **EXPLANATION**
- 23 The inclusion of this explanation does not constitute agreement with 24
- the explanation's substance by the members of the general assembly.
- 25 This bill relates to the electronic prescribing of
- 26 prescription drugs, including controlled substances.
- 27 bill requires all prescriptions for prescription drugs to
- 28 transmitted to a pharmacy electronically, effective July 1,
- The bill also requires prescriptions for controlled
- 30 substances that are issued electronically to comply with
- 31 federal law for the electronic transmittal of prescriptions
- 32 for controlled substances. The bill provides exemptions
- 33 from this requirement in certain circumstances and provides
- 34 alternative methods for the transmittal of prescriptions in
- 35 those circumstances and for prescriptions transmitted prior to

- 1 July 1, 2019. The bill also allows a person subject to the
- 2 requirements of the bill to petition the board of pharmacy
- 3 for exemption from the requirements of the bill based on
- 4 economic hardship, technical limitations, or other exceptional
- 5 circumstances. The bill requires refills for prescription
- 6 drugs and controlled substances to be transmitted in the same
- 7 manner as required for initial prescriptions.
- A practitioner who does not transmit a prescription
- 9 drug order electronically as required by the bill shall be
- 10 subject to an administrative penalty of \$250 per violation,
- 11 up to a maximum of \$5,000 per calendar year. Such a penalty
- 12 shall be assessed by the professional licensing board of the
- 13 practitioner alleged to have committed the violation. A
- 14 practitioner may contest such penalty, which shall initiate a
- 15 contested case proceeding under Code chapter 17A. Any such
- 16 penalty collected by a professional licensing board shall be
- 17 deposited into the drug information program fund and reported
- 18 to the board.
- 19 A person who does not comply with Code section 124.308
- 20 is guilty of an aggravated misdemeanor pursuant to Code
- 21 section 124.402. An aggravated misdemeanor is punishable by
- 22 confinement for no more than two years and a fine of at least
- 23 \$625 but not more than \$6,250.

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